IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON

WESTERN DISTRICT OF WASHINGTON AT TACOMA

MARGARET SANTOYO,

Plaintiff,

v.

HOWMEDICA OSTEONICS CORP., a New Jersey Corporation d/b/a STRYKER ORTHOPAEDICS,

Defendants.

Case No: **15-CV-05264 (BHS)**

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT HOC'S MOTION FOR PROTECTIVE ORDER

NOTED ON MOTION CALENDAR:
Friday, April 8, 2016

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I. INTRODUCTION

This is a product liability action arising out of Defendant Howmedica Osteonics Corp.'s ("HOC") Accolade hip implant system that caused such damage to Plaintiff that she had to have a complete revision of the original hip implant. Defendant HOC has asked the Court to limit Plaintiff's discovery requests so as to avoid responding to discovery regarding the metal femoral stem that combined with the metal head and caused corrosion and damage in Plaintiff's body and the need for a second surgery. Despite the clear allegations in the Petition the defect at issue relates to the combination of the metal femoral stem with the metal head, Defendant has decided for itself that Plaintiff's discovery requests regarding the femoral stem are not "at

Nash & Franciskato Law Firm
2300 Main Street, Suite 170
Kansas City, Missouri 64108
(816) 221-6600
(816) 221-6612 fax

issue". Defendant's argument is shockingly disingenuous as it misrepresents to the Court what Plaintiff's theories of liability are and the damage done from the corrosion caused by these two metal parts. When plaintiff's product liability claims are analyzed with regard to the facts of the case it is clear that plaintiff's discovery requests for documents relating to all parts of the defective hip implant system are appropriate topics for discovery. Therefore, Defendant's Motion for Protective Order must be denied.

II. FACTUAL BACKGROUND

A. Defendant's metal-on-metal hip implant system.

The Accolade hip implant system included a femoral stem made out of four types of metal: titanium, molybdenum, zinc and iron (hereinafter referred to as the "TMZF stem"). Plaintiff's First Amended Complaint ¶¶ 1, 18. The TMZF stem was attached to a metal ball or head made out of two metals, cobalt and chromium and is referred to as the "LFIT femoral head". Plaintiff's First Amended Complaint ¶¶ 1, 23. The use of a metal stem with a metal ball made the Accolade into a "metal-on-metal" hip implant system. The ball was then inserted into an artificial cup that is attached to the hipbone. ¶ 7.

The Accolade hip implant system was one of several known metal-on-metal hip systems manufactured by Defendant. The Rejuvenate and the ABG II systems were two other metal on metal systems designed for use with a TMZF stem. For decades, the scientific community has known about the potential dangers of combining titanium and cobalt/chromium in the body, as the combination of different metals can cause fretting and corrosion. (Plaintiff's First Amended Complaint ¶ 37). This can lead to adverse tissue reactions and the recipients can suffer pain, loosening of the system and tissue destruction. Plaintiff's First Amended Complaint ¶ 34.

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Kansas City, Missouri 64108
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(816) 221-6612 fax

Both the Rejuvenate and ABG II experienced high failure rates and Defendant was forced to recall those products on June 29, 2012. Plaintiff's First Amended Complaint ¶¶ 35-36. The recall was due to the increased likelihood of adverse local tissue reactions caused by fretting and corrosion around the junction of the stem and neck. Plaintiff's First Amended Complaint ¶47. At the same time, Defendant abandoned the use of the TMFZ stem in conjunction with the LFIT femoral head in the Accolade system. Plaintiff's First Amended Complaint ¶ 51.

B. Plaintiff's implantation and revision.

Plaintiff was implanted with Defendant's Accolade hip implant system, including a TMZF stem and a cobalt/chromium head on January 8, 2007 in her left hip. In July 2012, plaintiff's surgeon recommended she have the Accolade hip implant system replaced because of loosening. Plaintiff's First Amended Complaint ¶¶ 77, 78. During the surgery, the surgeon, Dr. Teeny, noted extensive corrosion inside Plaintiff from the metal-on-metal hip implants and described it as follows:

> "Immediately upon entering the joint, **a thick squirt of green, thick fluid was expressed seemingly under pressure**. …This was immediately sent to laboratory for a gram stain and evaluation with some synovial tissue for evaluation which showed minimal chronic inflammation. No acute inflammation. No signs of polymorphonuclear leukocytes. With that in mind, the feeling was it **had a clinical picture of an ALVAL type reaction**…We did a partial capsulectomy and capsulotomy which allowed us to express the femoral head. A bone tamp was used to remove it. It **noted a large amount of corrosion material at the trunnion and some deep, what appeared to be corrosion materials** deep inside the femoral head as well, even after head was removed. ….The cup itself was completely loose. …More green purulent-like material was found behind the cup along with **quite a bit of necrotic bone** so that a fair portion of the posterior wall, some of the superior wall, some of the anterior wall and inferiorly all with

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> significant bone loss. There was necrotic bone almost in a layer around the cup as well."

Plaintiff's First Amended Complaint ¶ 80 (emphasis added).

Dr. Teeny removed the cobalt/chromium head and replaced it with a ceramic head on the TMZF stem. Plaintiff's First Amended Complaint ¶ 81. Therefore, it was no longer a metal-on-metal hip system.

C. Plaintiff's Liability Theory.

To avoid responding to relevant discovery requests, Defendant mischaracterizes Plaintiff's theory of liability. Defendant argues that only hip replacement component devices on which discovery can be sought are those that "medical records indicate are at issue." Defendant's Motion at 1. Defendant then concludes that the TMZF is not at issue because it was not removed from Plaintiff's body and Plaintiff was not diagnosed with an Adverse Local Tissue Reaction. In so doing, Defendant completely ignores Plaintiff's actual theories of liability as set forth in the Complaint and misrepresents the medical records. It is the theories raised in Plaintiff's First Amended Complaint (none of which have been subject to a motion to dismiss or summary judgment) that control the appropriate scope for Plaintiff's discovery. Plaintiff's theories of liability clearly and directly implicate the TMZF stem; therefore, discovery about that product is directly relevant.

The overarching theory behind all of Plaintiff's product liability claims in this case is that the TMZF stem, when coupled with a cobalt/chromium head (i.e., a metal-on-metal hip implant system), creates a defective product that is known to cause fretting and corrosion inside the recipient's body. This can cause, and in Plaintiff's case, did cause an adverse tissue reaction and resulted in loosening of the acetabular cup and the need for a revision surgery.

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The product identified as defective in Plaintiff's First Amended Complaint includes the TMZF hip stem as well as the LFIT head. Plaintiff's First Amended Complaint ¶ 1. Plaintiff alleges that Defendant negligently and tortuously made statements that the combination of the TMZF and cobalt/chromium did not create concerns with fretting or corrosion, and they failed to warn about the dangers associated with the product. Plaintiff's First Amended Complaint ¶¶ 24, 39. Plaintiff alleges that the same TMZF stem combined with a cobalt/chromium neck were used in other similar products that had high failure rates and were eventually recalled because of complications from corrosion and fretting. Plaintiff's First Amended Complaint ¶¶ 32-43. Plaintiff alleged that one of the main effects of this corrosion caused by the combination of metal debris wear is an Adverse Local Tissue Reaction which "may include ***tissue death***…and infection" in the hip region. Plaintiff's First Amended Complaint ¶ 57 (emphasis added).

Contrary to Defendant's characterization, Plaintiff's First Amended Complaint clearly and specifically implicates the TMZF metal stem in combination with the cobalt/chromium LFIT head creating a defective product that has caused Plaintiff injury. Given the allegations in the Complaint, Defendant's argument that discovery regarding the TMZF stem should not be permitted is outrageous as it amounts to a backdoor attempt at disposing of Plaintiff's principle theory of liability without even filing a dispositive motion.

III. LEGAL ARGUMENT

A. Discovery on the TMZF stem is relevant to both Plaintiff's liability theory and Plaintiff's injuries.

While Defendant correctly supplies the Court with the proper authorities governing the entry of a protective order, it completely fails to meet its burden to justify the entry of a

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(816) 221-6600
(816) 221-6612 fax

protective order regarding the TMZF stem. Defendant's entire argument rests on the conclusion that the discovery sought concerning the TMZF stem is irrelevant. Defendant arrives at this conclusion on two contentions. First, the TMZF stem was left in Plaintiff. Second, the medical records do not contain a "diagnosis" that Plaintiff suffered an adverse local tissue reaction ("ALTR"). Defendant's first contention is simply irrelevant at it ignores Plaintiff's theory of liability. Defendant's second contention is simply wrong.

As discussed above, Plaintiff's primary theory of liability is the combination of different metals in Defendant's Accolade hip implant system, titanium in the TMZF stem and chromium/cobalt in the LFIT head, created the corrosion problem that caused Plaintiff injury. Amazingly, while Defendant relies heavily on the fact that the TMZF stem was left in Plaintiff's body, Defendant fails to tell the Court that the LFIT head was exchanged for a non-metallic, ceramic head. This switch to a non-metallic head alleviated the problem of having the different metals react together in a corrosive manner. Therefore, the fact that the TMZF remains in Plaintiff is completely irrelevant to Plaintiff's theory of liability. The TMZF stem still had a direct causal relationship with Plaintiff's injury and is an appropriate subject for discovery.

Defendant's second basis for avoiding discovery on the TMZF stem is that Plaintiff "never received a diagnosis of ALTR." Defendant's Motion at 4. This argument, while carefully worded, is spurious at best. The operative report cited above and attached to Defendant's motion, notes numerous abnormalities in Plaintiff's hip, none of which Defendant acknowledged to the Court.

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First, the surgeon performing the revision surgery noted that there was a green, thick "purulent" liquid in the area. Obviously, a green pus-like fluid in the hip is not normal and is evidence of a tissue reaction. Thus, the green fluid shown in the operative report is itself evidence of an adverse tissue reaction.

Second, the operative report notes "quite a bit of necrotic bone" and significant bone loss all around the hip area. Tissue and bone death is a type of ALTR. Plaintiff's First Amended Complaint ¶ 57. In fact, it is difficult to imagine a more adverse tissue reaction than death; again, this is evidence of an adverse tissue reaction.

Finally, the surgeon noted an ALVAL type reaction. ALVAL stands for an acute lymphocyte vasculitis associated lesion. This is a type of tissue reaction in which a mass-forming tissue reaction occurs around a metal-on-metal hip replacement. Therefore, the medical record indicates an additional type of adverse tissue reaction.

So, while there was no specific "diagnosis" of an ALTR, the operative report shows that Plaintiff suffered adverse tissue reactions including green like fluid, bone loss and a mass-forming lesion. These are precisely the type of injuries that occur from the combining the titanium TMZF stem with a cobalt/chromium LFIT head. These injuries have also occurred when the TMZF stem was used in the now-recalled cobalt/chromium Rejuvenate and ABG II. Consequently, discovery concerning the TMZF stem not only "may" lead to the discovery of admissible evidence, but also is highly likely to lead to such discovery. Therefore, Defendant has not met its burden for the entry of a protective order.

B. Defendant fails to meet its burden to show that the burden of Plaintiff's requests is disproportional to the benefit of production.

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Kansas City, Missouri 64108
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Defendant's argument that the discovery requests relating to the TMZF stem are disproportional is as weak as its claims of irrelevance. An examination of the factors in Rule 26(b)(1) together with the actual facts and allegations in the Complaint, do not show any undue burden on Defendant or any disproportionality.

1. The importance of the issues at stake.

The Accolade hip implant system, including the TMZF stem and LFIT head, is responsible for injuries to numerous patients. Defendant is already a defendant in dozens of cases involving the Accolade hip implant system and in even more cases involving the TMZF stem. Therefore, the discovery concerning the TMZF stem and its development and failure, is of critical importance in the pursuit of product defect cases involving the Accolade.

2. The amount in controversy.

Defendant claims the amount in controversy is "minimal" based solely on Defendant's contention that Plaintiff does not require further surgery or care. This claim is completely unsupported. Plaintiff has already incurred medical expenses of over $29,000 and lost wages of approximately $30,000. While these amounts may seem insignificant to attorneys who charge in excess of $400 per hour, they are substantial to Plaintiff. Additionally, she had an unnecessary and painful surgery due to Defendant's defective Accolade hip implant system and has incurred pain and suffering that no amount of money will remedy. Also, as a result of the failure of the Accolade hip implant system, Plaintiff is at greater risk to undergo another revision surgery in the future.

3. The parties' relative access to the information.

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The information sought concerning the TMZF stem is exclusively under the control of defendant. Plaintiff has no way to access this information except through discovery in this legal proceeding. As discussed above, should the Court preclude discovery on the TMZF stem it is tantamount to granting summary judgment on Plaintiff's product defect theory without the normal opportunities to respond to such a motion including the opportunity to conduct discovery on the issues.

Additionally, the Court should be made aware that Defendant's Rejuvenate and ABG II hip implant systems, both of which can use the TMZF stem, are subjects of a multidistrict litigation panel. The litigation is pending in an MDL created in the United States District Court for the District of Minnesota and is MDL No. 2441. The MDL has hundreds of plaintiffs and was created in 2013. In that litigation, the use of the TMZF stem combined with a cobalt/chromium modular neck and head was an issue in the case. Therefore, it is highly likely that Defendant has already produced or been asked to produce the same information regarding the TMZF stem in that MDL that Plaintiff seeks here. In which case, the production of the same materials here would constitute little to no burden at all.

4. The parties' resources.

Plaintiff Margaret Santoyo is 61 years old and works as a nurse in Washington. She was forced to miss three months of work due to the revision surgery. On the other hand, Defendant HOC is a multinational corporation that develops, manufactures and distributes many orthopedic products and services all over the world. Defendant HOC is a subsidiary of Stryker Corporation, a Fortune 500 company with annual revenues of over $9 billion and a market capitalization of $40 billion. Obviously, Defendant has sufficient resources to respond

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2300 Main Street, Suite 170
Kansas City, Missouri 64108
(816) 221-6600
(816) 221-6612 fax

to the discovery requests. Indeed, Defendant does not even address this factor in its Motion given the enormous disparity in resources between the parties.

5. The importance of the discovery in resolving the issues.

When the Court is given an accurate description of Plaintiff's theories and the facts of the case, it is obvious that discovery relating to the TMZF stem is of the utmost importance in resolving the product liability claims in this case. Plaintiff's primary theory of liability concerns the corrosion created from the use of the TMZF metal stem with different metal components in the hip implant system. Regardless of whether the stem remains in Plaintiff or not, Plaintiff still maintains the entire Accolade system, which includes the TMZF stem, was defective because of the metals used together.

6. Whether the burden or expense of discovery outweighs its likely benefit.

Defendant claims that the burden of production would be "substantial". Defendant's Motion at 10. However, Defendant provides *no estimation* either in worker hours or cost for justifying its claim. Defendant claims there may be thousands of pages of documents that are responsive to the discovery requests. However, many of these documents may already have been compiled in other litigation and their production may merely take a few computer keystrokes to produce. It was Defendant's responsibility to demonstrate the burden to the Court and its summary claims of burden are not sufficient to preclude production of documents concerning a key component in Plaintiff's product liability case.

Defendant also cites a burden in producing confidential and proprietary information that may be contained in the materials sought. This concern is easily dealt with and does not justify Defendant's refusal to produce the documents. If the information contains confidential or

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2300 Main Street, Suite 170
Kansas City, Missouri 64108
(816) 221-6600
(816) 221-6612 fax

proprietary information, the parties either agree to or seek a protective order that would bar disclosure outside of the litigation. In fact, the MDL for the Rejuvenate and ABG II has such a protective order to guard against the public disclosure of confidential information. Similarly, any confidential patient information could be redacted to avoid public disclosure. In fact, the parties are in the process of submitting an agreed upon protective order, addressing confidential and proprietary information.

IV. CONCLUSION

Defendant's request for a protective order must be denied. The TMZF stem is part of the entire Accolade hip implant system at issue in this case and is central to Plaintiff's liability theory. It was the use of the TMZF stem in conjunction with a cobalt/chromium head that resulted in the corrosion in Plaintiff's body and created her injuries and need for a revision surgery. Plaintiff's medical records show that she sustained multiple complications from this corrosion including the presence of thick green fluid, bone necrosis and lesions, all of which are known dangers of combining the different metals in the stem and head in a metal-on-metal hip implant system. This same defect with the TMZF stem when used in conjunction with chromium/cobalt in a hip implant system was present in two other of Defendant's hip implant systems both of which have been recalled and are subject of an MDL. Under Rule 26(b)(1), Plaintiff is absolutely entitled to discovery about these products when coupled with the same TMZF component as well as the component itself.

Defendant has also failed to prove its claim of disproportionality in arguing its need to be protected from Plaintiff's discovery requests. Defendant presented the Court with no estimate of the time or difficulty needed to produce the materials or the cost of production.

Nash & Franciskato Law Firm
2300 Main Street, Suite 170
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(816) 221-6600
(816) 221-6612 fax

Defendant has exclusive possession of the materials and has more than sufficient resources to provide the production. Any concerns about privacy or confidentiality can be addressed via a protective order that precludes public disclosure of the documents. Most importantly here, the TMZF stem is part of the entire defective product at issue. Plaintiff's ability to present evidence of the defect in this case would be seriously impaired without discovery on this key component that is integral to Plaintiff's causation theory.

For the foregoing reasons Defendant's Motion for Protective Order should be denied.

Dated this 1st day of April, 2016.

NASH & FRANCISKATO LAW FIRM

/s/ Brian S. Franciskato
Brian S. Franciskato, MO #41634
(Admitted Pro Hac Vice)
bfranciskato@nashfranciskato.com
Two Pershing Square
2300 Main Street, Suite 170
Kansas City, Missouri 64108
(816) 221-6600
FAX: (816) 221-6612

MAGLIO CHRISTOPHER & TOALE, PA
Altom M. Maglio, FL #88005
amm@mctplaw.com
1751 Mound Street, 2nd Floor
Sarasota, FL 34236
(941) 952-5242
Fax: (941) 952-5042

CRANE DUNHAM PLLC
Douglas S. Dunham, WSBA #2676
ddunham@cranedunham.com
Stephen J. Crane, WSBA #4932
scrane@cranedunham.com
2121 5th Avenue
Seattle, WA 98121-2510
(206) 292-9090
FAX: (206) 292-9736
Attorneys for Plaintiff Santoyo